§ 2.23 Patient access and restrictions on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a part 2 program from giving a patient access to their own records, including the opportunity to inspect and copy any records that the part 2 program maintains about the patient. The part 2 program is not required to obtain a patient's written consent or other authorization under the regulations in this part in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 2.12(d)(1).

Subpart C—Disclosures With Patient Consent

§ 2.31 Consent requirements.

(a) *Required elements for written consent.* A written consent to a disclosure under the regulations in this part may be paper or electronic and must include:

(1) The name of the patient.

(2) The specific name(s) or general designation(s) of the part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.

(3) How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.

(4)(i) The name(s) of the individual(s) to whom a disclosure is to be made; or

(ii) *Entities with a treating provider relationship with the patient.* If the recipient entity has a treating provider relationship with the patient whose information is being disclosed, such as a hospital, a health care clinic, or a private practice, the name of that entity; or

(iii) *Entities without a treating provider relationship with the patient.*

(A) If the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is a third-party payer, the name of the entity; or

(B) If the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is not covered by paragraph (a)(4)(iii)(A) of this section, such as an entity that facilitates the exchange of health information or a research institution, the name(s) of the entity(-ies); and

(*1*) The name(s) of an individual participant(s); or

(*2*) The name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or

(*3*) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.

(*i*) When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation (*see* § 2.13(d)).

(*ii*) [Reserved]

(5) The purpose of the disclosure. In accordance with § 2.13(a), the disclosure must be limited to that information which is necessary to carry out the stated purpose.

(6) A statement that the consent is subject to revocation at any time except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer

(7) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.

(8) The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign under § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.

(9) The date on which the consent is signed.

(b) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through reasonable diligence could be known, by the individual or entity holding the records to be materially false.

§ 2.32 Prohibition on re-disclosure.

(a) *Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by the following written statement: This information has been disclosed to you from records protected by federal confidentiality rules (*42 CFR part 2*). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is *NOT* sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.

(b) [Reserved]

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of their records under § 2.31, a program may disclose those records in accordance with that consent to any person identified in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments.

(a) *Restrictions on disclosure.* A part 2 program, as defined in § 2.11, may disclose patient records to a central registry or to any withdrawal management or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:

(i) The consent must list the name and address of each central registry and each known withdrawal management or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any withdrawal management or maintenance treatment program established within 200 miles of the program, but does not need to individually name all programs.

(b) *Use of information limited to prevention of multiple enrollments.* A central registry and any withdrawal management or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not re-disclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a